

**REMARKS**

In response to the Restriction Requirement dated March 18, 2008, Applicants hereby wish to elect the subject matter of Group II (claims 102-126) for continued prosecution in this application. Furthermore, Applicants wish to elect the following species:

1. Single disclosed 5-HT agonist - sumatriptan
2. Single disclosed carrier composition - binder
3. Single disclosed ternary buffer system - sodium carbonate, sodium bicarbonate, and amorphous magnesium oxide
4. Single dosage form - lozenge

Claims 1-101 have been canceled without prejudice. Applicants believe that claims 102, 104-117, and 119-126 read on the elected species.

**Amendments to the Claims**

Applicants have amended dependent claims 103-104 and 106-126 to change the preambles from "A method" to "The method." No new matter has been added with these amendments.

**Amendments to the Specification**

Applicants have requested amendments be made to paragraph [0001] ("CROSS-REFERENCES TO RELATED APPLICATIONS") to correct the relate-back statement. Please note that these corrections are required to be made in the specification only. A copy of the filing receipt is attached as Exhibit A to show that the correct applications were properly identified

when the corresponding international and subject application were filed. No new matter has been added with this amendment.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,  
O'MELVENY & MYERS LLP

Dated: May 13, 2008

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# **EXHIBIT A**

**COPY**

UNITED STATES PATENT AND TRADEMARK OFFICE

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 United States Patent and Trademark Office  
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| APPL NO.   | FILING OR 371<br>(c) DATE | ART UNIT | FIL FEE REC'D | ATTY. DOCKET NO | DRAWINGS | TOT CLMS | IND CLMS |
|------------|---------------------------|----------|---------------|-----------------|----------|----------|----------|
| 10/567,658 | 10/27/2006                | 1614     | 6565          | 022205-000320US | 2        | 120      | 9        |

CONFIRMATION NO. 2423

 20350  
 TOWNSEND AND TOWNSEND AND CREW, LLP  
 TWO EMBARCADERO CENTER  
 EIGHTH FLOOR  
 SAN FRANCISCO, CA 94111-3834

## FILING RECEIPT



\*OC000000021520597\*

Date Mailed: 12/08/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Nikhilesh N. Singh, Mill Valley, CA;

## Assignment For Published Patent Application

TRANSORAL PHARMACEUTICALS, INC., CORTE MADERA, CA

Power of Attorney: The patent practitioners associated with Customer Number **20350**.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US04/27156 08/18/2004  
 which claims benefit of 60/560,748 08/21/2003  
 and claims benefit of 60/598,672 08/03/2004

## Foreign Applications

If Required, Foreign Filing License Granted: 12/07/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/567,658**

Projected Publication Date: 03/15/2007

Non-Publication Request: No

**COPY**

115

Early Publication Request: No

**\*\* SMALL ENTITY \*\***

Title

Compositions for delivering 5-HT agonists across the oral mucosa and methods of use thereof

Preliminary Class

424

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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